

5215  
B2

--25. (new) A method for treating an injury to the skin or mucosa, which comprises applying to the injured site an effective amount of a composition comprising between about 10 and about 50 percent by weight of beeswax, a pharmaceutically-acceptable emollient and a pharmaceutically-acceptable excipient.--

--26. (new) The method of claim 24, wherein the injury is a burn.--

--27. (new) The method of claim 25, wherein the injury is a burn.--

#### REMARKS

This is in response to the Office Action mailed June 20, 2001, and is accompanied by a request for a three month extension of time.

#### Priority

The present amendment requests insertion of complete priority information.

#### 35 USC §101

Reconsideration and withdrawal of the rejection of claims 1-23 as being directed to non-statutory subject matter are respectfully requested. While applicant

respectfully disagrees that a "topical product" is non-statutory subject matter, claims 1-15, 17-18 and 22-23 are amended to recite compositions, which is believed and intended to be no narrower than topical products.

**35 USC §112, first paragraph**

Reconsideration and withdrawal of the rejection of claims 1-23 for lack of enablement are respectfully requested. Applicant respectfully disagrees that topical products are not enabled. However, to advance prosecution, claims 1-15, 17-18 and 22-23 now recite compositions, which the Examiner has acknowledged to be enabled.

**35 USC §112, second paragraph**

Reconsideration and withdrawal of the various rejections of the claims under the second paragraph of 35 USC §112 are respectfully requested.

First, while applicant respectfully disagrees that the metes and bounds of a "topical product" cannot be determined, to advance prosecution claims 1-15, 17-18 and 22-23 now recite compositions.

Next, claim 1 has been amended to make clear that the oleaginous base comprises the listed ingredients. Finally, claims 2, 10, and 12-14 have been amended to correct the

typographical errors noted by the Examiner. Claim 21 has been canceled as duplicative of claim 20.

**35 USC §102**

Reconsideration and withdrawal of the rejection of claims 1, 3, 6-9, 16, 17 and 19-22 under 35 USC §102(b) as being anticipated by Guillon are respectfully requested.

Guillon is directed to cosmetic compositions which include saponifiable fractions of vegetable or animal oils. In contrast, the present compositions are useful in the treatment of skin injuries, such as burns.

All composition claims recite a composition in which the oleaginous base comprises each of the following: olive oil, sunflower oil, almond oil, cod liver oil, castor oil and beeswax. Guillon discloses no such composition. The laundry list of at least 38 conventional cosmetic ingredients at column 2, lines 39-51 does not include beeswax, and certainly does not disclose or suggest beeswax in combination with olive oil, sunflower oil, almond oil, cod liver oil, and castor oil. Of the six specific formulations disclosed in Guillon, only two disclose beeswax (Examples 1 and 6), but neither one contains all of the other ingredients recited in claim 1. There is no anticipation. It is also clear that Guillon's disclosure

of cosmetic compositions cannot anticipate claims 24-27, which are directed to the treatment of injuries, such as burns.

Reconsideration and withdrawal of the rejection of claims 3, 4, 6-9, and 16-23 under 35 USC §102(b) as being anticipated by McGinity are respectfully requested. Preliminarily, McGinity is not available as prior art under §102(b) as its issue date (January 28, 1997) is later than applicant's October 30, 1995 and March 29, 1996 priority dates. Moreover, McGinity is directed to stick formulations for topical drug delivery. There is no disclosure of the combination of beeswax with olive oil, sunflower oil, almond oil, cod liver oil, and castor oil as recited in all composition claims. There is no anticipation. It is also clear that McGinity cannot anticipate claims 24-27, which are directed to the treatment of injuries, such as burns.

Reconsideration and withdrawal of the rejection of claim 1 under 35 USC §102(e) as being anticipated by Lane are respectfully requested. Lane is directed to lip balm compositions containing salt and aloe vera. There is no disclosure of the combination of beeswax with olive oil, sunflower oil, almond oil, cod liver oil, and castor oil as recited in all composition claims. The laundry list of

dozens of ingredients at column 4 does not disclose beeswax in combination with olive oil, sunflower oil, almond oil, cod liver oil, and castor oil. Moreover, Lane's examples likewise do not point to such a combination. In fact, none of the examples appears to utilize any of the claim 1 ingredients. There is no anticipation. It is also clear that Lane cannot anticipate claims 24-27, which are directed to the treatment of injuries, such as burns.

### **35 USC §103**

Reconsideration and withdrawal of the rejection of claims 1-17 and 19-23 under 35 USC §103 as being unpatentable in view of Guillon are respectfully requested. The differences between Guillon and the present claims are discussed above in connection with the §102 rejection. In view of those differences, the rejected claims would not have been obvious.

Reconsideration and withdrawal of the rejection of claims 1-17 and 19-23 under 35 USC §103 as being unpatentable in view of Lane are respectfully requested. The differences between Lane and the present claims are discussed above in connection with the §102 rejection. In view of those differences, the rejected claims would not have been obvious.

Reconsideration and withdrawal of the rejection of claims 1-23 under 35 USC §103 as being unpatentable over Guillon or Lane in view of McGinity are respectfully requested. The differences between Guillon, Lane and the present claims are discussed above in connection with the §102 rejection. McGinity, also discussed above, does not fill in the gaps, and the rejected claims would not have been obvious.

**Claim Objection**

Reconsideration and withdrawal of the objection to claim 21 are respectfully requested. The objection is moot as the claim has been canceled.

Applicant submits that the present application is now in condition for allowance. Reconsideration and favorable action are earnestly requested.

Respectfully submitted,



Glenn E. Karta  
Attorney for Applicants  
Registration No. 30,649  
ROTHWELL, FIGG, ERNST & MANBECK, p.c.  
555 Thirteenth Street, N.W.  
Suite 701 East Tower  
Washington, D.C. 20004  
Telephone: (202) 783-6040

MARKED-UP VERSION OF THE CLAIMS

--1. (amended) A [topical product] composition for application to the skin or mucosal surface, comprising

a) an oleaginous base [of] comprising olive oil, sunflower oil, almond oil, cod liver oil, castor oil and beeswax, and

b) a pharmaceutically-acceptable excipient [for topical application to the skin].--

--2. (amended) [A topical product] The composition of claim 1, [for application to the skin] comprising about 5% by weight olive oil, about 21% by weight sunflower oil, about 21% by weight almond oil, about 10% by weight cod liver oil, about 3% by weight castor oil and about 23% by weight beeswax, [the balance of said product comprising] and about 17% by weight of a pharmaceutically-acceptable excipient [for topical application to the skin].--

--3. (amended) The composition of claim 1, [A topical product for application to the skin] comprising between about 10 and about 50 percent by weight of beeswax[, a pharmaceutically-acceptable emollient for topical application to the skin and a pharmaceutically-acceptable excipient for topical application to the skin].--

--4. (amended) The [topical product] composition of [according to] claim 3, comprising between about 18 and about 27 percent by weight of beeswax.--

--5. (amended) The [topical product] composition of [according to] claim 3, comprising between about 23 and about 25 percent by weight of beeswax.--

--6. (amended) The [topical product] composition of [according to] claim 3, further comprising Vitamin A.--

--7. (amended) The [topical product] composition of [according to] claim 3, further comprising Vitamin D.--

--8. (amended) The [topical product] composition of [according to] claim 3, further comprising Vitamin E.--

--9. (amended) The [topical product] composition of [according to] claim 3, further comprising Vitamins A, D and E.--

--10. (amended) The [topical product] composition of [according to] claim 3, further comprising, per 100 g of the [topical product] composition, between about 1275  $\mu\text{g}$  and about 3825  $\mu\text{g}$  Vitamin A.--

--11. (amended) The [topical product] composition of [according to] claim 10, comprising about 2550  $\mu\text{g}$  Vitamin A per 100 g of the [topical product] composition.--

--12. (amended) The [topical product] composition of [according to] claim 3, further comprising, per 100 g of



the [topical product] composition, between about 10.625  $\mu$ g and about 31.875  $\mu$ g Vitamin D.--

--13. (amended) The [topical product] composition of [according to] claim 12, comprising, per 100 g of the [topical product] composition, [between] about 21.25  $\mu$ g Vitamin D.--

--14. (amended) The [topical product] composition of [according to] claim 3, further comprising, per 100 g of the [topical product] composition, between about 975 mg and about 3000 mg Vitamin E.--

--15. (amended) The [topical product] composition of [according to] claim 14, comprising, per 100 g of the [topical product] composition, about 2025 mg Vitamin E.--

--17. (amended) The [topical product] composition of [according to] claim 3, wherein the excipient comprises liquid petroleum jelly.--

--18. (amended) The [topical product] composition of [according to] claim 17, wherein the excipient further comprises stearic acid.--

--22. (amended) The [topical product] composition of [according to] claim 3, further comprising a preservative.--

--23. (amended) The [topical product] composition of  
[according to] claim 22, wherein said preservative is  
butylhydroxytoluene.--